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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,760	03/10/2004	Bill H. McAnalley	23100.65	4242

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EXAMINER	
FLOOD, MICHELE C	
ART UNIT	**PAPER NUMBER**
1655	

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/797,760	MCANALLEY ET AL.	
	Examiner	Art Unit	
	Michele Flood	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *1-4 and 9-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/19/05;12/12/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

This application contains claims 1-4 and 9-24 drawn to an invention nonelected with traverse on June 6, 2005. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

Claims 5-8 are under examination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5-8 as amended are rejected under 35 U.S.C. 103(a) as obvious over Murray et al. (UU1, Robert K. Murray et al., Harper's Biochemistry, Appleton & Lange, 1996, pages 648-666) in view of McAnalley et al. (AA1, U.S. Patent No. 5,308,838).

Applicant claims a dietary supplement composition comprising: a nutritionally effective amount of isolated and purified acetylated mannose; and a nutritionally effective amount of at least five isolated and purified saccharides selected from galactatose, glucose, mannose, xylose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine, arabinose, glucuronic acid, galacturonic acid, iduronic acid and arabinogalactan. Applicant further claims the dietary supplement of claim 5, wherein the five isolated and purified saccharides are powdered; wherein the five isolated and purified saccharides are essential saccharides; and wherein the five isolated and purified saccharides further comprise glucosamine and rhamnose.

On page 650, in Table 56-4, Murray teaches that galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine and xylose are the principal sugars found in human glycoproteins.

The teachings of Murray are set forth above. Although Murray teaches each of galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine and xylose as essential saccharides for building properly structured human glycoproteins, Murray does not teach a dietary supplement composition comprising a nutritionally effective amount of at least five of the aforementioned principal sugars and/or in combination with a nutritionally effective of isolated and purified acetylated mannose. However, it would have been obvious to one

of ordinary skill in the to combine a nutritionally effective amount of at least five isolated and purified of the saccharides taught by Murray with a nutritionally effective amount of isolated and purified acetylated mannose because at the time the invention was made to provide the instantly claimed dietary supplement composition because Murray taught that the at least five claim-designated saccharides of the Markush group recited in Claim 5 were the principal building blocks of glycoproteins found in humans and important in the phenomenon of activity against metastasis, especially metastasis in cancer cells; and, McAnalley taught a composition comprising acetylated mannose, that is acemannan derived from aloe, which is effective in treating a number of disease conditions where the principal mechanism of resolution or cure system requires intervention by the immune system. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to combine a nutritionally effective amount of at least five isolated and purified of the saccharides taught by Murray with a nutritionally effective amount of the isolated and purified acetylated mannose taught by McAnalley to provide the instantly claimed dietary supplement composition for the following reasons: Firstly, Murray teaches that galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine and xylose are the principal sugars found in human glycoproteins, which have numerous and diverse biological functions, as set forth in Table 56-2. Furthermore, on page 665 to 666, under "*SUMMARY*", Murray teaches, "The oligosaccharide chains are important to glycoproteins in modulating their solubility and viscosity, in protecting them against

proteolysis, in their biologic actions, and in their participation in normal and abnormal cell-cell interactions (*e.g.*, sperm-egg interaction, development, and cancer, respectively.). Secondly, McAnalley teaches that a composition comprising acetylated mannose is effective for treating cancer, viral diseases, respiratory and immune diseases, inflammations, and infestations by administering an effective amount of an acetylated mannan derivatives, such as acemannan derived from aloe

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add any of the claimed ingredients in the making of the claimed composition because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten,* 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi,* 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett,* 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

With regard to the limitations of Claim 6 wherein Applicant directs the instantly claimed invention to a dietary supplement composition wherein the at least five isolated and purified saccharides are powdered, at the time the invention was made, it also would have been obvious to one of ordinary skill in the art and one would have been motivated and one would have had a reasonable expectation of success to combine the instantly claimed ingredients in powdered form because the claim-designated form is no more than a conventional pharmaceutical form for the delivery of an active agent. Thus,

at the time the invention was made the choice of combining the claim-designated saccharides in the form of a powder would have been merely a matter of design choice to one practicing the invention given that the claimed form is a conventional form to deliver a drug.

With regard to the limitations of Claim 8 wherein Applicant directs the claimed invention to additional isolated and purified saccharides, as acetylglucosamine is a source of glucosamine, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to substitute one for the other in the making of the instantly claimed composition to substitute one functional equivalent for the other.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 5-8 as amended are rejected under 35 U.S.C. 103(a) as obvious over Murray et al. (UU1, Robert K. Murray et al., Harper's Biochemistry, Appleton & Lange, 1996, pages 648-666) and McAnalley et al. (AA1, U.S. Patent No. 5,308,838) in view of Yamada et al. (NN1, JP 1995113001 A).

Applicant's claimed invention was set forth above.

The combined teachings of Murray and McAnalley are set forth above. The combined teachings of Murray and McAnalley do not teach a dietary supplement further comprising glucosamine and rhamnose. However, it would have been obvious to one of

ordinary skill in the art at the time the invention was made to add either isolated and purified glucosamine and rhamnose to the composition taught by the combined teachings of Murray and McAnalley because Yamada taught a dietary supplement comprising arabinose, galactose, glucose, rhamnose, galacturonic acid and glucuronic acid. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the dietary supplement taught by Yamada to the dietary supplement taught by the combined teachings of Murray and McAnalley because Yamada taught that the referenced dietary supplement improves hematopoietic function and serves as a radioprotective agent for treating or reducing the risk of radiation injury.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add any of the claimed ingredients in the making of the claimed composition because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten,* 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi,* 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett,* 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

No claims are allowed.

Conclusion

Applicant's submission of information disclosure statements under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on September 19, 2005 and December 12, 2005, and prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm. I

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHELE FLOOD
PRIMARY EXAMINER

Michele Flood
Primary Examiner
Art Unit 1655

MCF
January 9, 2006